International Journal of Technology Assessment in Health Care, **16:4** (2000), 1003–1012.

THE DEVELOPMENT OF EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES

Integrating Medical Science and Practice

Richard T. Connis
David G. Nickinovich
American Society of Anesthesiologists

Robert A. Caplan
University of Washington

James F. Arens
M.D. Anderson Cancer Center

Abstract

Practice guidelines are rapidly becoming preferred decision-making resources in medicine, as advances in technology and pharmaceutics continue to expand. An evidence-based approach to the development of practice guidelines serves to anchor healthcare policy to scientific documentation, and in conjunction with practitioner opinion can provide a powerful and practical clinical tool. Three sources of information are essential to an evidence-based approach: a) an exhaustive literature synthesis; b) meta-analysis; and c) consensus opinion. The systematic merging of evidence from these sources offers healthcare providers a scientifically supportable document that is flexible enough to deal with clinically complex problems. Evidence-based practice guidelines, in conjunction with practice standards and practice advisories, are invaluable resources for clinical decision making. The judicious use of these documents by practitioners will serve to improve the efficiency and safety of health care well.

Keywords: Practice guidelines, Evidence-based medicine

Practice guidelines in medicine have traditionally been created as policy documents that serve as information resources for the systematization of clinical practice. Their intended purpose is to provide physicians and other healthcare professionals with a useful reference for optimizing patient care. Because guidelines are usually developed and endorsed by a healthcare organization with the intent of regulating or standardizing clinical decision making (4;6), the broadest possible base of evidence is critical to their development. A broad evidence base will include a comprehensive assessment of peer-reviewed scientific literature combined with interpretations based on the clinical experience of practitioners (27).

Historically, the use of scientific literature in the development of practice guidelines has been selective rather than systematic. Prior to the 1980s, literature reviews were typically narrative, with the search process driven by the subjective judgment of reviewers (20;25). This "traditional" approach to literature review is often limited by the reviewers' knowledge of the literature and inclusion of a disproportionate number of articles supportive of the reviewers' viewpoints (8;18). According to Chalmers and Lau (3).

> Too often, authors of traditional review articles decide what they would like to establish as the truth either before starting the review process or after reading a few persuasive articles. They then proceed to defend their conclusions by citing all the evidence they can find. The opportunity for a biased presentation is enormous, and its readers are vulnerable because they have no opportunity to examine the possibilities of biases in the review.

Evidence-based approaches have the potential to avoid systematic bias through the combination of a structured, exhaustive evaluation of scientific documentation and an assessment of diverse practitioner opinion (5). The application of quantitative techniques and precise rules to combine research findings from various independent studies bolsters the scientific rigor of the aggregated literature with meta-analysis as the primary approach. However, it is important to note that meta-analytic results alone can be misinterpreted as easily as the results of an individual study. An evaluation of scientific documentation in the appropriate clinical context is aided by surveys and other documented opinions from experts and practicing healthcare providers.

In applying meta-analytic and other scientific findings, the information provided by the practice guideline in the form of recommendations needs to be flexible enough to accommodate the complexities of clinical practice. Analytic evidence may indicate that a treatment or other intervention is effective. However, a guideline recommendation needs to allow for the clinical judgment of the practitioner, who determines whether the intervention is medically warranted or appropriate for a specific case. An additional source of evidence is needed in developing a guideline, and is best obtained by evaluating information based on the clinical experiences of experts and practitioners. Scientific knowledge can then be meaningfully combined with clinical judgment to develop recommendations for the application of a designated intervention (28). A guideline must also be feasible for use in a wide range of practice settings, meaning that scientific evidence and expert opinion should be supplemented by opinions from the broader population of practitioners (27). This broad base of opinion can benefit the development and implementation of a guideline in two ways. First, input from a variety of practice settings (e.g., large academic institutions and small rural settings) may contribute to a guideline's flexibility by identifying issues and problems unique to each distinct setting. Second, constructive forums for the expression of divergent opinions prior to a guideline's formal implementation enhance a guideline's acceptance by the general membership of a medical specialty.

The purpose of this paper is to define and describe elements of a multifaceted guideline development process currently used by the professional association of one medical specialty, the American Society of Anesthesiologists (ASA). The ASA has published 10 evidence-based practice guidelines, including guidelines for difficult airway management, acute pain, chronic pain, cancer pain, preoperative fasting, and obstetrical anesthesia (2;7;9;10;13;14;19;21;23;24). These guidelines have been well received.

Practice guidelines were developed by the ASA to address issues that could not be reasonably addressed by practice standards. Practice standards typically provide specific requirements for practice and are applied, with few exceptions, to virtually all relevant clinical situations. Although standards are important prescriptions for anesthesia care, it was recognized that more complex topics warranted a less rigid approach. Practice guidelines

were recognized as tools for providing clinical recommendations that would address these broader topics. Because of the complexity of the issues addressed, it was necessary for guidelines to incorporate a comprehensive array of evidence, including detailed assessments of the scientific literature and consensus documentation from multiple sources.

IDENTIFICATION OF GOALS AND OBJECTIVES

ASA's evidence-based guidelines generally take 1–3 years to develop, and include a number of important steps before final completion and approval (Table 1). Typically a policy committee or task force is convened, consisting of academic and clinical practitioners recognized as experts in the topic of concern and representing a variety of practices and

Table 1. Protocol for Practice Guideline Development

1. Committee/task force assignment
2. Identification of potential evidence linkages
3. Literature search
   a. Articles considered (original studies or reports published in peer-reviewed journals)
      1) Randomized controlled trials
      2) Nonrandomized comparative studies
      3) Controlled observational studies
      4) Retrospective comparative studies
      5) Uncontrolled observational studies
      6) Case reports
   b. Articles not considered
      1) Letters with no original data
      2) Editorials, review articles, and commentaries
      3) Meta-analytic studies (these analyses use data generated from other studies)
      4) Personal correspondence
      5) Unpublished papers/presentations
4. Availability of scientific evidence in the literature is determined. If none of the evidence linkages has sufficient literature at this point in the process, a decision is made to either revise the evidence linkages or produce a practice advisory.
5. Literature synthesis with assessment of directional evidence
   a. Review and sort studies into potential evidence linkage categories
      1) Record relevant information related to clinical factors (e.g., patient health status, clinical interventions used, health outcomes).
      2) Code information related to statistical evidence (e.g., study design, statistical tests, significance levels)
   b. Assign directional support for a potential evidence linkage addressed by each selected study (some studies address multiple linkages). For each study, determine direction related to patient benefit (positive, negative, or neutral).
   c. Determine overall direction of support for evidence linkage by summation of individual studies.
6. Hypothesis development
   a. Assess overall linkage directions.
   b. Determine one-tailed hypotheses based on linkage direction.
7. Meta-analysis: Adequately designed studies with sufficient quantitative information to describe a statistical relationship between a clinical intervention and a clinical outcome are identified.
   a. Randomized controlled trials
   b. Nonrandomized comparative studies (conditionally acceptable)
8. Consensus assessment
   a. Surveys related to evidence linkages
      1) Expert consultants
      2) Broad representation of practitioners
   b. Feasibility surveys
   c. Open forum presentations
   d. Internet commentary
9. Formal review and approval by specialty organization

geographic areas. This broad representation leads to improved chances of generalizing the final recommendations.

The task force begins the process by formalizing the intended topics, goals, and objectives for the proposed guideline. These items include a description of the clinical disorders and conditions to be addressed by the guidelines, the types of patients for whom the guidelines are intended, clinical interventions (e.g., diagnostic tests, treatments) that will be considered in developing the guidelines, the principal intended users of the guidelines, and the practice settings in which the guidelines are applicable. These formalized topics play a crucial role in defining the scope of the guideline. Once the formalized topics, goals, and objectives are identified and agreed upon by the task force, an evidence model is formulated. The evidence model specifies criteria for inclusion/exclusion of data from the literature or other sources.

DEVELOPING AN EVIDENCE MODEL

Following specification of the guideline's goals and objectives, a series of potential evidence linkages is formulated (26). Evidence linkages represent statements about relationships between clinical interventions and clinical outcomes. A clinical intervention is typically an activity performed by a physician or other healthcare provider (e.g., administering a specified drug). A clinical outcome is recorded in terms of its potential benefit to the patient (e.g., reduced pain or minimization of specified side effects). An important component of an evidence linkage is the specificity of the identified interventions and outcomes. For example, "analgesics provide maternal pain relief" would be further specified with a statement such as "epidural bupivacaine with opioids affects maternal analgesia during labor." This specification of targeted interventions and outcomes, in conjunction with other elements from the evidence model (e.g., intended providers, targeted patient population), will provide definitive direction for obtaining, organizing, and evaluating the evidence.

This evidence model provides the framework for a guideline's clinical recommendations, and essentially provides the structure for the entire development process. Once the model is in place, the task force can initiate a multistep process. The elements of this process will include literature searches, literature syntheses, meta-analyses, survey development, consensus evaluation, feasibility studies, open-forum presentations, Internet commentary, and formal endorsement by the society or healthcare organization.

LITERATURE SEARCH FOR EVIDENCE

The literature search usually includes a computerized search of large reference sources, such as the National Library of Medicine or Nursing and Allied Health Abstracts. Other electronic resources, also readily available on CD-ROM and/or the Internet, contain databases of reviews and abstracts as well as full-text articles. Software for bibliographic reference databases is an important tool in the search process, citation management, and dissemination of findings. Manual searches of literature are conducted to supplement electronic sources. Since electronic searches are typically driven by keyword search engines, they do not always have appropriate search mechanisms to locate relevant topics of interest.

To be useful for evidence-based guideline development, studies must meet certain criteria. First, a study must report a clinical finding or set of findings that can be tallied or quantified. This requirement eliminates reports that contain only commentary or undocumented opinions of the authors. Second, a study must be an original investigation or report containing a clinical finding or set of findings. Thus, review articles or manuscripts that report findings from other sources are not used. For meta-analytic evidence, study findings

must clearly indicate a specified relationship between a clinical intervention and an outcome of interest.

After the first phase of article search and classification is completed, a listing of all articles located to date is presented to the task force. Members are asked to review all articles listed, both those accepted and those not accepted, and to suggest changes in the acceptance or nonacceptance of individual articles when needed. They also may add articles not listed, to refine and expand the search process.

Some practice guidelines developed by other organizations may include unpublished literature as potential evidence assessment. Use of such literature addresses the issue of sampling or "publication" bias, in which journals may be biased toward accepting articles that report statistically significant findings (25). As a result of such bias, many manuscripts reporting nonsignificant findings or no differences between groups or conditions are not accepted for publication. Often, upon discovering that they have no significant findings, investigators may not bother to submit a manuscript for publication (i.e., a "file-drawer" problem) (15).

Although publication bias is a viable concern, ASA investigators do not currently use unpublished literature as a source of data for several reasons. Unpublished studies are not peer-reviewed and the use of such literature may incorporate data derived from inadequate research methods, the use of inappropriate or flawed statistical procedures, and other problems usually identified and corrected by the peer-review process. In addition, investigators do not know whether the obtained sample of unpublished studies is representative of the relevant population of unpublished literature. Therefore, this potential for selection bias is as serious a threat as that of publication bias. Although some research groups have endeavored to create repositories of unpublished studies, the completeness of such databases remains questionable. In lieu of obtaining a representative sample of unpublished studies, standard statistical methods (e.g., computation of a "fail-safe" N value) are available and provide a reasonable estimate of the required number of additional (i.e., unpublished) studies reporting contradictory outcomes sufficient to nullify the findings obtained from published studies (16;25).

LITERATURE SYNTHESIS WITH DIRECTIONAL ASSESSMENT

Evidence linkages are initially used for purposes of identifying relevant literature. This literature is reviewed and detailed information is extracted, including but not limited to patient data (e.g., clinical condition, age); data regarding the treatment, procedure, or anesthetic intervention: outcomes reported; and research design and statistical analyses. Spreadsheet technology applied to this task is invaluable, particularly in the subsequent management of the data and summarization of findings. The use of such technology can greatly reduce the time and effort spent aggregating the data.

In their spreadsheet documentation, the ASA includes a classification value of the predominant "direction" of study findings. For each reviewed study, the outcome of interest is classified as supporting a linkage, refuting a linkage, or neutral. Each article is coded (i.e., support $= +1$, refutation $= -1$, neutral $= 0$), and a summary value is calculated across all studies. From these results, a directional (one-tailed) assessment of support or refutation for each linkage is obtained. Following the directional assessment, the evidence linkages are revised to include directionality, therefore providing justification for the use of one-tailed statistical testing. A directional statement derived from the evidence linkage example cited earlier would be: "epidural bupivacaine with opioids *improves* maternal analgesia during labor compared to equal concentrations of epidural bupivacaine without opioids." All studies with data, regardless of methodology, are included in the directional assessment. No attempt is made to calculate average values or other aggregate statistics.

The directional overview of the literature is viewed as a tool to refine the evidence linkage in order to initiate statistical procedures (i.e., meta-analyses). The directional assessment represents a separate and vital component of the literature-based evidence because it is an examination of all studies, including those for which effect size estimates are not provided (i.e., case reports, descriptive studies, correlational studies). These studies are important to evaluate because they contain information not necessarily found elsewhere, and their inclusion can affect the directional assessment. For example, case reports may provide an indication of adverse outcomes or previously unrecognized benefits not recorded in the clinical trial literature. Moreover, descriptive studies provide evidence related to the frequency of occurrence of an adverse or beneficial outcome when an intervention of interest is employed.

ANALYTICAL PREPARATION

Once the directional overview is complete, the evidence linkages are refined to include one-tailed hypotheses so that formal meta-analyses can proceed. At this point, only controlled comparative studies are considered for analysis. Controlled studies provide a vital indication of the effectiveness of a medical intervention.

In the meta-analytic procedures utilized by the ASA, the primary interest has been to combine original (primary) research studies for purposes of investigating questions of causality. In this effort to document causal relationships, the design features of the various studies under review are of critical importance. If the studies comprising the primary research literature have design features that assure a high level of internal validity (e.g., random assignment of subjects to conditions of the study, researcher and practitioner blinding, and researcher control over the intervention), then questions regarding causality can be addressed. When threats to internal validity are evident in the primary studies under review (e.g., treatments administered to pre-existing groups), then analyses cannot directly address questions of causality and are limited to questions of covariation. In summary, literature review can generally determine associations between variables of interest, but the investigation of questions of causality is critically dependent on the inferential robustness of the controlled studies under review.

ANALYTICAL MODEL

Meta-analysis

When an evidence linkage contains a sufficient number of studies (e.g., five or more) with well-defined experimental designs and statistical information, formal meta-analyses are conducted. A fixed-effects model using odds ratios or combined probability tests is applied when there is an expectation of minimal variation in effect size estimates among the studies in the analysis.

A fixed-effects model is used more commonly for several reasons. Historically, the anesthesia literature has used the same or very similar outcome measures (e.g., visual analog scale scores for pain measurement). Variability in outcomes among the various independent studies has generally been homogeneous. Conceptually, directional nonrandom outcomes are generally expected in the anesthesia literature. On occasion, a random-effects model may be considered when appreciable effect size variability is expected.

Usually, more than one test statistic is obtained in a meta-analysis related to a particular evidence linkage. For a meta-analysis to be supportive of an evidence linkage, all component analyses must be in agreement regarding effect sizes and significance values. As a further assurance of the congruity and robustness of the findings, all meta-analyses

should be in agreement with the directional assessment as well as with consensus opinion. When agreement is not apparent in any of the specified areas of evidence, further evaluation is necessary, and, if the disagreement continues to persist, the discrepancy is reported and discussed in the guideline.

Methodologic controls

As a methodologic control for reviewer bias, additional assessments of the reviewed literature are conducted independently by the task force members and methodologists. The ASA uses a sample of reviewed articles randomly selected from each evidence linkage and a random sample of articles not accepted into the database to assess agreement for study design, type of statistical analysis, identification of evidence linkage, and the reviewers' judgment as to whether the study should be included in the database. Interobserver agreement among task force members and methodologists is assessed and reported using agreement levels for two-rater agreement pairs (17) and for multi-rater chance-corrected agreement (11;12).

Following review of the literature, tests for heterogeneity of findings from the independent studies are conducted to ensure consistency among the study results. To control for potential publishing bias, the ASA calculates a fail-safe N value for each combined probability test. A fail-safe N refers to the number of additional studies necessary to increase the overall probability value obtained to a value higher than the critical value for statistical significance (16). To ensure that the literature considered is peer-reviewed, no search for unpublished studies is conducted. The ASA does not conduct reliability tests for locating research results, because their intent is to obtain an entire population of published studies for each evidence linkage rather than collecting a representative sample of studies.

CONSENSUS AS EVIDENCE

Research findings from published literature provide the cornerstone for guideline recommendations. However, published studies alone may not provide necessary or complete information regarding relevant details of clinical practice. Accordingly, additional sources of information and evidence are actively and deliberately sought by the ASA. Such information may best be obtained from clinical experience. For example, studies examining preoperative testing may provide information about the sensitivity and specificity of a particular test without providing insight about when or on whom a test should be performed. Practitioner opinions may serve this role as a supplemental source of evidence, reflecting current practice. Topics that are addressed by obtaining practitioner opinion include issues related to the importance and practicality of the interventions identified in a guideline, and issues related to the projected cost, estimated practice time, and feasibility of implementing a guideline. Practitioner opinion may be obtained through several mechanisms, ranging from the simple recording of consensus within a designated task force to large-scale surveys and feedback from presentations or open forums at national conventions.

The ASA obtains consensus data from multiple sources, including surveys of expert consultants and of the broader population of practitioners, and open forum presentations, Internet commentary, and feasibility studies. Expert consultants are carefully chosen to provide a balance between private practice and academia, as well as representation from each of the major geographic areas of the United States. Consultants are asked to participate in surveys of their opinions of various aspects of a guideline and to review and comment on initial draft reports. Random samples of the ASA membership are also surveyed regarding the topics addressed by the evidence linkages.

Each task force holds one or more open forums at a major national anesthesia meeting to solicit input on its draft guideline from meeting attendees. During each open forum, audience

testimony is recorded. Directly following an open forum, the task force meets, commentary is discussed, and clarifications in the draft document may be made. Major issues, when they arise, may require a new literature synthesis or additional consensus surveys. The revised draft is then disseminated to various additional sources (e.g., the Internet, ASA district directors, presidents of ASA component societies) for their commentary. The consultants are surveyed one final time to assess their opinions on the feasibility of implementing the revised guideline recommendations. All available information is used by the task force to produce a final document for submission to the ASA for formal approval.

The term *consensus* in this sense refers to an evaluation of the combined agreement derived from the sampling of opinions from scientists, experts, academicians, and clinicians. Surveys used to elicit and measure these opinions are designed so that responses are easily interpreted and differences, when they occur, are clearly noted. The opinions of survey respondents are based on sets of items that are deliberately the same for each group of respondents. Responses from several sources can thus be conveniently compared.

Each consensus survey item is derived from a specific evidence linkage. Since the evidence linkages are also employed in the literature search and assessment procedures, the same set of intervention/outcome relationships provides a constant foundation throughout the entire guideline development process.

The use of consensus as a source of evidence has not been thoroughly explored. However, consensus data often provide critical feedback on the feasibility of the proposed recommendations. "Consensus as evidence" is a relatively distinct component of ASA's process. These data are analyzed in the same manner as directional evidence, and thus become the third major evidence source for the formulation of viable recommendations.

GUIDELINE RECOMMENDATIONS

Guideline recommendations are based directly on the evidence linkages developed at the beginning of the process. Each of the three sources of evidence (i.e., directional, meta-analytic, and consensus) is separately considered in the formulation of the final recommendations.

Agreement among the three sources of evidence is required for the full support of a recommendation related to a particular evidence linkage. Occasionally, divergence from the full support of all three sources may occur. For example, meta-analytic and directional results may support a designated intervention, but their application in clinical practice may be questioned by consensus findings. These divergences are noted, then discussed and interpreted in the guideline. By discussing the strengths and shortcomings of each recommendation, a guideline becomes sufficiently dynamic to respond to the diverse requirements of clinical practice.

CONCLUSIONS

The process described herein represents the collective efforts by the ASA to produce timely and clinically relevant guidelines. In particular, the use of an exhaustive literature search, literature synthesis, directional summarization, meta-analyses, and consensus assessment all combine to produce a multifaceted overview of evidence for rational policy decision making in clinical medicine. These activities are made easier and more accurate through the use of existing technology, such as reference databases (for literature searches and citation management), spreadsheets (for literature aggregation and analysis), and statistical software (for survey assessment).

The ASA's evidence-based model for guideline development combines literature synthesis and analysis with the knowledge and experience obtained from clinical practice. The accumulated scientific data coupled with the recognition that practitioners on occasion

may need to modify procedures to fit individual cases forms a compelling basis for the widespread acceptance and use of practice guidelines.

When there is not sufficient information available for the development of an evidence-based practice guideline, an alternative may be considered. One alternative that has recently been implemented by the ASA is the practice advisory (1;22). The intent of a practice advisory is to systematically use an evidence-based model without meta-analytic findings. Therefore, until meta-analytic evidence becomes available, a practice advisory, in the form of a published report, may be used as a viable reference document for clinical practice.

Through the dissemination of practice advisories in conjunction with practice standards and guidelines, the ASA makes available a complete package of advice to clinicians on selected topics. Practice standards offer guidance for narrow and well-defined areas of practice, while guidelines and advisories are intended to address the more complex aspects of patient care and may provide information on the impact of new medical technologies or other recent interventions. These three sources of guidance, when periodically updated, will offer practitioners access to the most recent collective knowledge relating to patient care.

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